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10/791,075	03/01/2004	David W. Wieting	212/560	2977

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EXAMINER	
DEAK, LESLIE R	
ART UNIT	PAPER NUMBER
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,075	WIETING ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *17-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7, 10, 12-14, 16, and 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/0110485 A1 to Stringer et al.

In the specification and figures, Stringer discloses the device as claimed by applicant. With regard to claim 1, Stringer discloses a blood handling system with gas removal comprising an axially elongate shell or housing 40 defining several chambers, including central void or chamber 51 (see FIG 3, paragraphs 0042-0044). The device further comprises an impeller 75 that is connected to drive unit or motor 32, a gas vent 46 located at a central axis of the shell or housing, a blood inlet port 41, and a blood outlet port 42 located at the radial periphery of the shell or housing (see FIG 3).

Applicant claims that the impeller is "operable to" rotate a volume of blood within the shell, creating a centrifugal force within the blood, causing the air bubbles to act in a particular manner. Applicant's claim language requires only that the prior art is *capable* of operating as claimed (applicant's recitation that the impeller is "operable to" perform a function means only that it is able to, or capable of performing the claimed function). Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood)

until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059). As such, the Stringer device is capable of operating as claimed by applicant, meeting the limitations of the claims.

With regard to claim 2, Stringer discloses that blood inlet 41 is located tangentially to the centerline of the housing or shell 40 (see paragraph 0046).

With regard to claim 3, Stringer discloses that the device comprises a baffled support structure 58 that is axially elongate, corresponding to applicant's claimed baffle (see FIG 3, paragraph 0048).

With regard to claims 4 and 5, applicant claims that the motor is electrically driven and that the motor and impeller are capable of rotating the impeller at a claimed RPM. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the motor disclosed by Stringer is capable of being electrically driven, and Stringer discloses that electrical lines may power the disclosed invention (see paragraph 0077). Furthermore, while Stringer is silent as to the rotational speed of the impeller, there is no disclosure indicating that the disclosed device may not operate as claimed by applicant, indicating that the Stringer impeller is capable of operating at the claimed RPM. Therefore, the Stringer device is capable of operating as claimed by applicant, meeting the limitations of the claims.

With regard to claim 6, Stringer discloses that the gas vent 46 may be connected to a gas suction source 34, corresponding to applicant's claimed gas pump (see paragraph 0042).

With regard to claim 7, Stringer discloses a filter element 85 is disposed at the entrance to blood outlet manifold 47, which connects to blood outlet 42, meeting the limitations of the claims (see paragraph 0058).

With regard to claim 10, Stringer illustrates that blood inlet port 41 is located higher than blood outlet port 42 (see FIG 3).

With regard to claim 12, Stringer illustrates that gas outlet port 46 is located at the top of the housing 40, higher than the blood inlet port 41 and blood outlet port 42 (see FIG 3).

With regard to claims 13 and 14, Stringer discloses that the impeller 75 may be magnetically coupled to drive unit 32 and comprises a plurality of vanes 76 (see paragraph 0052).

With regard to claim 16, Stringer discloses that the gas removal port or vent 46 comprises a gas collection plenum 50 that collects or traps gas before venting, meeting the limitations of applicant's claim drawn to a gas trap (see paragraph 0046).

With regard to claim 24, Stringer discloses the shell, impeller, motor, vent, inlet, and outlet as claimed by applicant. Applicant further sets forth limitations drawn to the operation of the device. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does

not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Stringer discloses that the impeller 75 is mounted on shaft 77 that is concentric with the axis of the shell, indicating that the impeller is capable of rotating as claimed by applicant, driven by motor or dive unit 32 (see paragraph 0052, 0061). Similarly, Stringer discloses that the device receives blood through inlet 41 from a patient via venous line 11 and delivers treated blood (including blood from which bubbles have been removed via gas removal system) to the patient through outlet 42 via arterial line 12 (see paragraph 0039, 0042). The Stringer device comprises applicant's claimed gas vent 46 that vents gas collected in the center axis of the shell (see FIG 3). Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059). Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas collection plenum, located at the center of the device (see paragraph 0059). As such, the Stringer device is capable of operating as claimed by applicant, meeting the limitations of the claims.

With regard to claim 25, With regard to claims 13 and 14, Stringer discloses that the impeller 75 may be magnetically coupled to drive unit 32 (see paragraph 0052). With regard to the manner of rotation, Stringer illustrates the impeller as contained entirely within shell or housing 40 (see FIG 3), indicating that the magnetic coupling

between the impeller 75 and drive unit 32 is capable of rotating the impeller through the housing or shell 40, meeting the limitations of the claim.

With regard to claims 26 and 27, Stringer discloses that the apparatus is intended to be part of an extracorporeal bypass system, indicating that the blood inlet port 41 and blood outlet port 42 are connected to blood handing system 30 (see FIG 1, paragraph 0038).

With regard to claims 28 and 29, applicant further sets forth limitations drawn to the operation of the device and the movement of blood therethrough. Such statements are considered by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the instantly claimed invention from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas collection plenum, located at the center of the device (see paragraph 0059). Furthermore, Stringer discloses that blood exits the device via blood outlet manifold 47 and blood outlet 41, located away from the gas collection plenum 50, minimizing gas/blood contact. Since Stringer suggests that the disclosed device is capable of operating as claimed by applicant, it meets the limitations of the claims.

With regard to claim 30, applicant claims a "means for adding," a "means for impelling," a "means for venting," and a "means for removing." The language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim

limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for " or "step for; "

(B) the "means for " or "step for " must be modified by functional language; and

(C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification. Applicant's specification provides reasonable support for the "means for" limitations above, indicating that the structure that performs the claimed functions comprise a blood inlet, an impeller, a gas vent, and a blood outlet.

Stringer specifically discloses a blood treatment device with a housing or shell 40, blood inlet 41, impeller 75, gas vent 46, and blood outlet 42, thereby meeting the structural limitations of the claim. With regard to applicant's recitation of the action of the impeller, the Stringer device comprises applicant's claimed gas vent 46 that vents gas collected in the center axis of the shell (see FIG 3). Stringer discloses that the impeller 75 and construction of the housing 40 cause the blood to rotate about the chamber (thus creating a centrifugal force within the blood) until air or other gases entrained in the blood separate from the blood and collect in the upper portion of the housing (see paragraphs 0058-0059). Stringer discloses that blood enters the device and circulates around gas removal filter 56 (indicating a spinning motion), collecting gas in the gas

collection plenum, located at the center of the device (see paragraph 0059). As such, the Stringer device meets the limitations of the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 6,264,601 to Jassawalla et al.

In the specification and figures, Stringer discloses the device substantially as claimed by applicant (see rejection above) with the exception of the blood outlet extending tangentially from the housing or shell of the device.

Jassawalla discloses a ventricular assist device with a pumping portion that comprises an inlet and outlet to move blood through the treatment device. The inlet and outlet conduits 24, 26 and ports 54, 60, are both located tangentially from the cylindrical pumping chamber 20 (see column 7, lines 51-67). The tangential orientation of the ports 54, 60 are selected to most efficiently fill and evacuate the chambers of the pumping device. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the blood outlet of the Stringer device in a tangential orientation to the housing as disclosed by Jassawalla in order to provide

efficient filling and evacuation of the chambers of the treatment device, as taught by Jassawalla (see column 7, lines 51-67).

5. Claims 9 and 15 are is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 6,769,871 to Yamazaki.

In the specification and figures, Stringer discloses the device substantially as claimed by applicant (see rejection above) with the exception of an antithrombogenic coating and a smooth impeller surface.

Yamazaki discloses a blood pump that circulates a patient's blood extracorporeally and prevents thrombus formation with an antihrombogenic coating made of a phospholipids bilayer and a small surface roughness. The coating is located on all surfaces that come into contact with the blood to reduce thrombus formation (see column 2, lines 5-30). The smooth impeller surfaces provide further thrombus suppression since blood will flow smoothly through the pump device (see column 3, lines 1-13). Therefore, it would have been obvious to one having ordinary skill in the art to provide the blood treatment and pumping device disclosed by Stringer with an antithrombogenic coating and smooth impeller surfaces as disclosed by Yamazaki, in order to prevent thrombus formation and allow long term deployment of the pump, as taught by Yamazaki (see column 2, lines 23-28).

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0110485 A1 to Stringer et al in view of US 5,823,987 to Elgas et al.

In the specification and figures, Stringer discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of placing the blood inlet

lower than the blood outlet. Elgas discloses an extracorporeal blood treatment device with a blood inlet 30 at the bottom of the device and a blood outlet 32 located above the inlet (see FIG 4). The position of the inlet and outlet provide a blood flow path that minimizes trauma to the blood cells and provides improved blood flow designed to minimize recirculation and stagnant areas (see column 2, lines 19-25). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to reverse the position of the blood inlet and outlet disclosed by Stringer in order to provide a blood path that minimizes recirculation and stagnant areas, as taught by Elgas (see column 2, lines 19-25).

Response to Arguments

7. Applicant's arguments filed 16 January 2007 have been fully considered but they are not persuasive.

8. Applicant argues that the Stringer device does not impart rotational motion to the blood in the system. However, as presented above, Stringer specifically discloses that rotational motion of the blood within the device helps to separate entrained gases from the rotating blood (see paragraph 0058). Blood enters gas collection plenum 50 via inlet 41, and swirls around the central void 51 as drawn by impeller 75, which imparts centrifugal energy to the blood (see paragraphs 0058-0061). Note that in FIG 3, impeller is fluidly connected to the blood and gas separation area via filter 59. Pump space 55 extends upwards to central void 51 via filter 59 (see also paragraph 0052). As the blood swirls around central void 51 and filter 59, bubbles escape the swirling blood and exit at

the central axis of the device at gas outlet 46. As such, Stringer discloses a device that uses an impeller fluidly connected to a gas collection chamber wherein the impeller imparts centrifugal motion to the blood to remove gases from the circulating blood.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 3,768,726 Hale et al

i. Centrifugal pump for removing entrained gases from liquids

b. US 2006/0084836 Hubbard et al

ii. Gas removal from a centrifugal pump

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
15 March 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER